COVID-19 VACCINE SCREENING AND IMMUNIZATION DOCUMENTATION

OMB No. 0720-0068
OMB approval expires: August 31, 2024

PRIVACY ACT STATEMENT

AUTHORITY: DHA-IPM 20-004, "DoD Coronavirus Disease (COVID-19) Vaccination Program Implementation"; Public Law 104-191, 10 U.S.C., Chapter Ch. 55, Medical and Dental Care;

PURPOSE: To determine if the COVID-19 vaccine can be administered to the patient.

ROUTINE USES: Information in your records may be disclosed to other components within the MHS for the purpose of continuing medical care and determining military readiness. Additionally, this information may be shared with the Departments of Veterans Affairs and Health and Human Services and other local, state, and federal public health agencies for the purposes of satisfying public health and vaccination reporting requirements and responding to the COVID-19 pandemic.

Any protected health information (PHI), including mental health and substance abuse information, in your records may be used and disclosed generally as permitted by the HIPAA Privacy Rule (45 CFR Parts 160 and 164), as implemented within DoD by DoDM 6025.18. Permitted uses and disclosures of PHI include, but are not limited to, treatment, payment, and healthcare operations. A complete listing of the applicable routine uses may be found in the associated System of Records Notice (SORN).

APPLICABLE SORN: EDHA 07, Military Health Information System (June 15, 2020, 85 FR 36190) https://dpcld.defense.gov/Portals/49/Documents/Privacy/SORNs/DHA/EDHA-07.pdf

DISCLOSURE: Voluntary. If you choose not to provide your information, no penalty may be imposed, but there may be a delay in the appropriate medical entry in your electronic health record.

1. NAME *(Last, First, Middle Initial)*	2. DoD ID or Unique Identifier	3. DATE OF BIRTH *(YYYYMMDD)*	4. AGE

5. CATEGORY: ☐ Service Member ☐ Beneficiary ☐ Civilian Contractor ☐ Civilian Employee ☐ Other

PART I – COMPLETED BY PATIENT	**YES**	**NO**
(1) Would you like to speak with a healthcare team member before receiving the COVID-19 vaccine?	☐	☐
(2) Are you currently sick, feel ill, or have a fever over 100°F?	☐	☐
(3) Have you received a COVID-19 vaccine before? If so, which one _____ Date _____	☐	☐
(4) Have you had an adverse or allergic reaction to a prior COVID vaccine, anaphylaxis due to any cause, or allergic reaction to any other vaccine or injectable therapy?	☐	☐
(5) Do you have hemophilia or other bleeding disorder or take a blood thinner?	☐	☐
(6) Do you have a history of/or a risk factor for a blood clotting disorder?	☐	☐
(7) Are you, or might you be, pregnant or are you nursing (breastfeeding)?	☐	☐
(8) Do you have an immunocompromising condition (HIV/AIDS, cancer, leukemia, etc.) or take an immunocompromising medicine or treatment (steroids, chemotherapy, radiation therapy, etc.)?	☐	☐
(9) Will you be TDY/TAD/PCS OCONUS for > 30 days within the next 30 days?	☐	☐
(10) Are you planning to receive other vaccines in addition to COVID-19 vaccine, today? (While it is a CDC best practice to administer multiple vaccines at a single visit, it is currently unknown whether the response to the COVID-19 vaccination will be affected by the co-administration of other vaccines.)	☐	☐
(11) Have you received a monoclonal antibody preparation or Convalescent Plasma within the past 90 days?	☐	☐

6. ACKNOWLEDGMENT I have read or had explained to me the information in the Coronavirus Vaccine Emergency Use Authorization (EUA) Fact Sheet or the Vaccine Information Fact Sheet for COMIRNATY /Pfizer-BioNTech COVID-19 Vaccine . I have also had a chance to ask questions for myself and/or child, including vaccine co-administration, if applicable. Questions were answered to my satisfaction and all options were reviewed and I agree to vaccination today

a. PATIENT / GUARDIAN SIGNATURE: _____ b. DATE: _____

PART II – COMPLETED BY SCREENER

7. ASSESSMENT

☐ Pfizer ☐ Moderna ☐ Janssen
☐ Dose #1 ☐ Dose #2 ☐ Dose #3
☐ Do not give COVID-19 vaccine today.
☐ Refer to experienced provider for further evaluation

8. Vaccine Information Material provided *(check box)*

☐ EUA Vaccine Fact Sheet for Vaccine Recipients of Janssen or Moderna COVID-19 Vaccine

☐ Vaccine Information Fact Sheet for Recipients of COMIRNATY or Pfizer-BioNTech COVID-19 Vaccine

9. SCREENER INFORMATION

a. NAME b. DATE *(YYYYMMDD)*

PART III – COMPLETED BY VACCINATOR

10. VACCINE ADMINISTERED

☐ Pfizer COVID-19 vaccine (≥ 12 yrs of age) 0.3mL IM
☐ Moderna COVID-19 vaccine (≥ 18 yrs of age) 0.5mL IM
☐ Janssen (J&J) COVID-19 vaccine (≥ 18 yrs of age) 0.5mL IM

11. LOT #: _____

12. EXPIRATION DATE: *(YYYYMMDD)* _____

13. DOSE: ☐ 0.3 mL IM ☐ 0.5 mL IM

14. SITE: ☐ Left Deltoid ☐ Right Deltoid

15. COMMENTS:

16. VACCINATOR INFORMATION a. NAME: b. DATE: *(YYYYMMDD)*

17. ASIMS / MEDPROS / MRRS / AHLTA / MHS GENESIS Entry a. NAME: b. DATE: *(YYYYMMDD)*

Information for Healthcare Professionals about Screening Questions

(1) Would you like to speak with a healthcare team member before receiving the COVID-19 vaccine?

These are new vaccines for which there are, understandably, many questions. The potential vaccinee should be afforded ample opportunity to read the FDA-provided EUA Vaccine Fact Sheet and to ask questions prior to vaccination. The staff will not hesitate to refer an individual to an experienced healthcare provider to address questions or concerns regarding the vaccine.

(2) Are you currently sick, feel ill, or have a fever over 100°F?

People with moderate or severe illness should not be vaccinated until their symptoms improve. Mild illnesses, even with fevers or requiring antibiotics, should not preclude receipt of COVID-19 vaccine. There is no evidence that acute illness reduces vaccine efficacy or increased vaccine adverse events.

(3) Have you received a COVID-19 vaccine before? If so, which one_____? Date_____?

The CDC recommends that different brands of COVID-19 vaccine not be mixed. Therefore, every effort should be made to ensure that when a vaccinee receives the first shot of one brand of vaccine that he/she be able to receive the same brand about 21-28 days later. If an individual is a participant in a COVID-19 Vaccine Trial, they should indicate 'yes' to this question and for "which vaccine" state "UNKNOWN". Direct such trial participants to contact their Study's Director to learn whether they received the active vaccine or an inactive placebo and to receive further counseling and guidance from the Study Director before receiving an authorized COVID-19 vaccine. If a study participant chooses to receive the authorized vaccine, it is recommended these two different COVID-19 vaccines be separated by a minimum of four weeks.

(4) Have you had an adverse or allergic reaction to a prior COVID vaccine, anaphylaxis due to any cause, or allergic reaction to any other vaccine or injectable therapy?

Patients reporting a serious reaction to a previous dose of COVID-19 vaccine, any vaccine, or injectable therapy (intramuscular, intravenous, or subcutaneous), should be asked to describe their symptoms. There is a remote chance that a COVID-19 vaccine could cause a severe allergic reaction. (1) Persons who have had a severe allergic reaction to the first dose of an mRNA COVID-19 vaccine should not receive a 2nd mRNA COVID-19 vaccine. However, consideration may be given to vaccination with Janssen COVID-19 vaccine under the supervision of a health care provider experienced in the management of severe allergic reactions, such as an Allergist. (2) An allergic reaction to any other vaccine or injectable therapy (such as chemotherapeutic agents) is a precaution to COVID-19 vaccination. Such individuals should be counseled that the risk of COVID-19 vaccine is unknown, and they should seek the advice of a medical specialist. If these individuals, or those with a history of anaphylaxis for any other cause, elect to be vaccinated, they should be observed for 30 minutes afterward. (3) A history of a significant, non-anaphylactic, reaction to a non-injectable medicine, food, latex, or pollen allergy does not preclude receipt of a COVID-19 vaccine. Mild-to-moderate non-allergic, flu-like symptoms, or vaccination site reactions are not a reason to withhold future vaccination. However, moderate-to-severe non-allergic reactions should be evaluated by an experienced provider prior to vaccination.

(5) Do you have hemophilia or other bleeding disorder or take a blood thinner?

People with bleeding disorders or treated with blood thinners should be counseled that they may have an increased risk of developing a hematoma following any intramuscular injection. If feasible, intramuscular vaccination may be delayed until shortly after anti-hemophilia therapy or alternation in their blood thinner regimen. Alternatively, a fine needle (≤ 23 gauge) can be used for vaccination and firm pressure applied to the site (without rubbing) for at least 2 minutes.

(6) Do you have a history of/or a risk factor for a blood clotting disorder?

For a patient history of blood clots with low platelet count, CDC recommends considering a vaccine other than Janssen if available. For all other types of clotting disorders, the Janssen vaccine is acceptable. All Janssen vaccine recipients should read the Janssen EUA Fact Sheet regarding symptoms of blood clots.

(7) Are you, or might you be, pregnant or are you nursing (breastfeeding)?

Vaccination is recommended for all people aged 12 years and older, including people that are: Pregnant, breastfeeding, or trying to get pregnant now or who might become pregnant in the future. A growing body of evidence on the safety and effectiveness of COVID-19 vaccination - in both animal and human studies - indicates that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy. If a person becomes pregnant following the first dose of a COVID-19 vaccine that requires two doses (i.e., Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine), the second dose should be administered as indicated for the person to have maximum protection. Pregnant, breastfeeding, and post-partum people 18 through 49 years of age should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 Vaccine and the availability of other FDA authorized COVID-19 vaccines (i.e., mRNA vaccines).

(8) Do you have an immunocompromising condition (HIV/AIDS, cancer, leukemia, etc.) or take an immunocompromising medicine or treatment (steroids, chemotherapy, radiation therapy, etc.)?

Immunocompromised individuals should be counseled that neither the safety nor efficacy of the COVID-19 vaccines have been studied in individuals with weakened immune systems resulting from congenital defect, disease, medications, or treatments. Non-live COVID-19 vaccines (those currently approved or under study in the US) may be administered to immunocompromised patients, although the protective benefit may be suboptimal. Vaccinated immunocompromised individuals need to continue to follow all current guidance to protect themselves against COVID-19. An additional dose (3rd) is currently only recommended for individuals who previously received an mRNA vaccine.

(9) Will you be TDY/TAD/PCS OCONUS for > 30 days within the next 30 days?

The CDC recommends that different brands of COVID-19 vaccine not be mixed. Therefore, every effort should be made to ensure that when a vaccinee receives the first shot of one brand of vaccine that he/she be able to receive the same brand about 21-28 days later. Extended OCONUS travel within 30 days of the first vaccination generally precludes this. Therefore, if such travel is planned, if the screener cannot ensure the 2nd dose with same brand can be administered at new location, initiation of vaccination should be deferred to the new location.

(10) Are you planning to receive other vaccines in addition to COVID-19 vaccine, today?

COVID-19 vaccines and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day, as well as co-administration within 14 days. It is unknown whether reactogenicity of COVID-19 vaccine is increased with co-administration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines. When deciding whether to co-administer another vaccine(s) with COVID-19 vaccine, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of vaccines. Prior to co-administration, patients will be advised of the above and reminded that vaccination with a FDA EUA COVID-19 vaccination is voluntary. Requests by vaccine recipients to receive EUA COVID-19 vaccination separate from other vaccinations must be accommodated.

(11) Have you received a monoclonal antibody preparation or Convalescent Plasma within the past 90 days?

Currently there is no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, however the ACIP recommends that COVID-19 vaccination be deferred for 90 days after receipt to avoid a possible impact on COVID-19 vaccination by prior antibody treatment. However, providers and patients can consider COVID-19 vaccination in such treated individuals within this 90-day window on a case-by-case basis with shared clinical decision-making for Force Health Protection and other important vaccination needs.

The Defense Health Agency-Immunization Healthcare Division (DHA-IHD) is available to 24/7 to assist patients and healthcare providers with clinical concerns at 877-438-8222, DSN 761-4245.